

**UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA**

TAKEDA PHARMACEUTICAL COMPANY
LIMITED, TAKEDA AMERICAS HOLDINGS,
INC., TAKEDA PHARMACEUTICALS U.S.A.,
INC., and TAKEDA DEVELOPMENT
CENTER AMERICAS, INC.,

Plaintiffs,

v.

CAREMARK RX, LLC,

Defendant.

Miscellaneous Case No. 2:23-mc-111

Underlying Action pending in the United
States District Court for the Southern District
of New York, *In re Actos Antitrust Litig.*
(Coordinated Actions), Case No. 1:13-cv-
09244-RA-SDA

**TAKEDA’S MEMORANDM OF LAW IN SUPPORT OF ITS MOTION
TO COMPEL CAREMARK RX, LLC TO COMPLY WITH ITS RULE 45 SUBPOENA
DUCES TECUM**

Pursuant to Federal Rule of Civil Procedure 45, Plaintiffs, Takeda Pharmaceutical Company Limited, Takeda Americas Holdings, Inc., Takeda Pharmaceuticals U.S.A., Inc., and Takeda Development Center Americas, Inc. (collectively, “Takeda”) respectfully request that this Court issue an Order compelling Defendant Caremark Rx, LLC (“Caremark”) to produce documents in response to the Subpoena to Produce Documents, Information, or Objects or to Permit Inspection of Premises in a Civil Action dated March 29, 2022 properly served upon it on March 30, 2022 (the “Subpoena”).

I. FACTUAL BACKGROUND

The Subpoena was served in *In re Actos Antitrust Litig.* (Coordinated Actions), No. 1:13-cv-09244-RA-SDA (the “Actions”), which comprises two related, coordinated putative antitrust class action lawsuits concerning Takeda’s drug ACTOS. The Actions are currently pending in the United States District Court for the Southern District of New York. *See* Declaration of Rachel J. Rodriguez, Esquire (“Rodriguez Decl.”), ¶¶ 3-6.

More than fifteen months ago, Takeda, defendants in the Actions, served the Subpoena on Caremark, one of the largest pharmacy benefit managers (“PBMs”) and a non-party to the Actions. In October 2022, Caremark participated briefly in the meet-and-confer process, after which Caremark’s counsel offered various excuses to avoid scheduling another meet-and-confer, and then simply stopped responding to Takeda altogether. Caremark has not communicated with Takeda in nearly six months and, despite failing to serve timely objections—or any objections at all—it has entirely failed to produce any documents responsive to the Subpoena.

A. The Actions

As relevant to this motion, the Actions concern allegations that Takeda engaged in conduct that plaintiffs claim delayed competitors from launching a generic version of ACTOS, thereby causing plaintiffs to purportedly pay higher prices for ACTOS between 2011 and at least 2013. *Id.*, ¶ 4.

In the first of the two coordinated Actions, *In re Actos End-Payor Antitrust Litig.*, No. 13-cv-09244 (S.D.N.Y.), the plaintiffs (“EPP Plaintiffs”) seek to represent a class of indirect purchasers of brand and generic ACTOS who allege that Takeda’s listing of certain patents in the FDA’s *Orange Book* caused them to pay higher prices, in violation of state antitrust laws. *Id.*, ¶ 5. In the second of the two Actions, *In re Actos Direct Purchaser Antitrust Litig.*, No. 15-cv-03278 (S.D.N.Y.), the plaintiffs (“DPP Plaintiffs”) seek to represent a putative class of direct purchasers of brand and generic ACTOS, who claim that they paid higher prices in violation of federal antitrust laws based on that same alleged conduct. *Id.*, ¶ 6.

By an agreement between the parties that was approved by the Court, discovery is coordinated in the Actions. *Id.*, ¶ 3.

B. Caremark’s Role As A PBM

PBMs are third-party companies that, among other things, manage prescription drug

benefits on behalf of health insurers, Medicare Part D drug plans, large employers, and other payers. PBMs negotiate pricing with drug manufacturers, set formularies (lists of approved medications that a health plan will cover), and process pharmacy claims. As such, PBMs have significant influence in determining total drug cost for health and benefits plans (such as those used by the EPP Plaintiffs), the amounts paid primarily to pharmaceutical wholesalers (such as the DPP Plaintiffs), and even which medications patients are able to access.¹

Caremark possesses information that would allow Takeda to analyze whether the putative classes are properly defined, determine whether plaintiffs suffered antitrust injury, and assess the relevant antitrust market. Rodriguez Decl., ¶ 8. For example, the requested data on payments Caremark made to its customers (e.g., rebates, discounts, pricing guarantees) in connection with ACTOS or generic ACTOS would enable Takeda to determine the real-world net payments made by potential third-party payor class members. *Id.*, ¶ 8(a). Likewise, the requested prescription claims data would enable Takeda to determine whether consumers who paid a flat copay for ACTOS or generic ACTOS (who are excluded from the EPP Plaintiffs' putative class) can be reasonably identified, as well as assess the real-world spending levels of putative class members. *Id.*, ¶ 8(b). By way of further example, the requested pharmaceutical & therapeutics committee minutes ("P&T Minutes") would enable Takeda to determine which products Caremark considered to be reasonable substitutes for ACTOS, which determination is relevant to whether plaintiffs' alleged relevant product market is legally cognizable. *Id.*, ¶ 8(c).

Furthermore, obtaining relevant information from Caremark is especially important

¹ "Pharmacy Benefit Managers and Their Role in Drug Spending," *The Commonwealth Fund* (Apr. 22, 2019), available at <https://www.commonwealthfund.org/publications/explainer/2019/apr/pharmacy-benefit-managers-and-their-role-drug-spending> (last visited July 26, 2023).

because of the nature of the PBM industry and Caremark's role in it.² During the relevant period, it was estimated that the two biggest PBMs, Express Scripts (45%) and Caremark (28%), controlled nearly three-quarters of the PBM market.³ Thus, the information sought from Caremark is not only relevant, but a significant fraction of all such information that exists can be found in Caremark's files.

C. Takeda's Efforts to Enforce the Subpoena

On March 30, 2022, Takeda's counsel served the Subpoena on Caremark. Rodriguez Decl., Ex. B. The Subpoena contained twenty-three (23) requests for the production of documents, with the relevant time period for discovery running from January 1, 2009 through December 31, 2015. *See id.*, Ex. A. Caremark never served objections to the Subpoena.

When Caremark through its counsel, Richard S. Davis of Foley & Lardner LLP, initially demonstrated a willingness to participate in the meet-and-confer process, Takeda twice proposed to narrow the scope of the Subpoena voluntarily and without Caremark demonstrating that compliance with the Subpoena would cause an undue burden. *Id.*, Exs. D, E, & F. Soon thereafter, Mr. Davis resorted to offering a myriad of excuses as to why he could not meet and confer, and he then stopped responding to Takeda entirely.

In late May to early June 2022, Takeda's counsel continued to follow up with Mr. Davis via email regarding compliance with the Subpoena and had one meet-and-confer with him. *See* Rodriguez Decl., ¶ 12. On or around June 1, 2022, Mr. Davis informed Takeda's counsel that he

² "Beyond the Big Three PBMs," *Managed Healthcare Executive* (Dec. 14, 2022), available at <https://www.managedhealthcareexecutive.com/view/beyond-the-big-three-pbms> (noting that in 2021 that Caremark was one of the three largest PBMs in the United States) (last visited July 26, 2023).

³ Abelson Reed & Natasha Singer, "F.T.C. Approves Merger of 2 of the Biggest Pharmacy Benefit Managers," *N.Y. Times* (Apr. 2, 2012), available at <https://www.nytimes.com/2012/04/03/business/ftc-approves-merger-of-express-scripts-and-medco.html> (last visited July 26, 2023).

would be willing to share with Caremark a letter from Takeda specifying a limited amount of documents responsive to the Subpoena along with the specific bases under which Takeda was requesting these documents. *See* Rodriguez Decl. ¶ 13.

On August 25, 2022, despite Caremark's failure to present evidence of undue burden or expense, Takeda's counsel sent an email to Mr. Davis that proposed to further limit the scope of Takeda's discovery requests (the "August 25 Letter") in accordance with Mr. Davis's request of June 1, 2022. *See* Rodriguez Decl., Ex. C at 8 (email) & Ex. D (the August 25 letter). In the August 25 Letter, Takeda offered to significantly reduce the scope of the Subpoena, which included decreasing the number of requests for production of documents from 23 requests to 6 categories of documents, or information corresponding to 9 requests. *Id.* Takeda also reduced the relevant time period over which documents were requested by *four years* for 7 of the 9 requests, and by two years for the remaining 2 requests. *Id.* Finally, the August 25 Letter outlined the reasons why *each* of the remaining categories of requested information are highly relevant to Takeda's potential defenses in the Actions. *Id.*

On September 7, 2022, Caremark's counsel, Mr. Davis, responded to the August 25 Letter via email. *See* Rodriguez Decl., Ex. C at 7. Mr. Davis indicated that Caremark found even this significantly reduced version of the requested documents to be "very broad" and requested a meet-and-confer after September 14, 2022. *Id.* The following day, Takeda's counsel and Mr. Davis exchanged emails agreeing on a September 20, 2022 meet-and-confer, which Mr. Davis later re-scheduled to September 28, 2022. *Id.* at 5-7.

On September 28, 2022, Takeda's and Caremark's respective counsel met and conferred. *See* Rodriguez Decl., ¶ 19. During this meeting, Takeda's counsel elaborated on the relevance of the requested documents and again indicated Takeda's willingness to further narrow the scope of the Subpoena, without compromising Takeda's ability to obtain information that is critical to its

defense. *Id.* Mr. Davis indicated that Caremark generally viewed Takeda's requests as information that could be obtained elsewhere, such as from the named EPP or DPP Plaintiffs, and emphasized in particular Caremark's reluctance to produce prescription claims data and P&T Minutes. *Id.* He stated, however, that he would take all requests back to his client for consideration, and that Caremark might be willing to produce formularies in lieu of P&T Minutes. *Id.*

On October 10, 2022, Takeda sent another letter (the "October 10 Letter") via email to Caremark, requesting that it produce documents as required in the Subpoena. *See Rodriguez Decl.*, Ex. C at 4-5 (email) & Ex. E (October 10 Letter). This letter proposed to narrow the requests even further and further limited the relevant time periods. *Id.* In this letter, Takeda also elaborated on the reasons why the requested information is relevant to Takeda's potential defenses in the Actions. *Id.*

On October 21, 2022, Takeda's counsel sent an email following up on the October 10 Letter and inquiring about Mr. Davis' availability for a meet-and-confer in the next week to resolve existing disputes. *See Rodriguez Decl.*, Ex. C at 4. A week later, on October 28, 2022, Mr. Davis responded with an apology for the delay, and promised to provide his availability for a meet-and-confer after he returned to his office on November 7, 2022. *See Rodriguez Decl.*, Ex. C at 4.

On November 4, 2022, Takeda's counsel sent another letter via email to Mr. Davis (the "November 4 Letter"), which corrected a minor error in the October 10 Letter, but was otherwise identical to it. *See Rodriguez Decl.*, ¶ 22, Ex. C at 3-4 (email) & Ex. F (November 4 Letter). Caremark's attorneys did not respond to the November 4 Letter or the email which sent it. *See Rodriguez Decl.*, ¶ 22 & Ex. C at 3.

On November 18, 2022, Takeda's counsel sent a follow-up email asking if there was anything to discuss in a meet-and-confer before the upcoming Thanksgiving holiday weekend. *Rodriguez Decl.*, ¶ 24 & Ex. C at 3. Caremark's attorneys did not respond to this email. *Rodriguez*

Decl., ¶ 24.

On January 3, 2022, Takeda's counsel sent Caremark's attorneys another follow-up email pointing out that the parties had not had a meet-and-confer since September 2022, and that the then-discovery deadline in the Actions was soon approaching, and requested that Caremark's counsel at least respond to Takeda's numerous emails. *See* Rodriguez Decl., Ex. C at 3. More than a week later, on January 9, 2023, Mr. Davis responded by promising to follow up after reviewing the November 4 Letter—which at that point he had for more than two months. *See id.*

On January 20, 2023, Takeda's counsel emailed Mr. Davis again, asking for an update on Caremark's efforts to comply with the Subpoena. *See id.* at 2. The email further noted that Caremark was significantly behind in its compliance compared to other PBMs that Takeda had subpoenaed in the Actions—which by then had all agreed in principle to produce, among other things, reasonably accessible prescription claims data. *See id.*

On January 27, 2023, Mr. Davis responded to Takeda's counsel's email of January 20, 2023, stating that one of his partners would be joining him on the next call to discuss matters addressed in the November 4 Letter and that he would follow up with proposed dates and times for such a discussion. *See id.* To date, neither Mr. Davis nor anyone else on behalf of Caremark has responded to further communications from Takeda. Rodriguez Decl., ¶ 25.

On February 3, 2023, Takeda's counsel sent Mr. Davis a follow-up email to see if he had checked with his colleague about times for a meet-and-confer. *Id.* Caremark's attorneys failed to respond. *See* Rodriguez Decl., ¶ 26 & Ex. C at 1-2. On February 15, 2023, Takeda's counsel sent Mr. Davis and his colleagues another follow-up email asking whether Caremark's attorneys intended to participate in the meet-and-confer process and pointing out that Takeda's attorneys had been attempting to schedule a meeting with them since October 2022. *See* Rodriguez Decl., Ex. C at 1. Takeda's counsel advised that Takeda was prepared to enforce its rights with respect

to the Subpoena by motion practice if necessary. Rodriguez Decl., ¶ 27 & Ex. C at 1.

On May 3, 2023, Takeda's counsel sent Mr. Davis and his colleagues yet another follow-up email that pointed out that counsel had ample time to review the October 10 and November 4 Letters, requested that they advise Takeda about their availability for a meet-and-confer, and advised that if Takeda did not hear from Caremark by May 10, 2023, it would assume Caremark's silence indicated that the parties are at impasse. *See* Rodriguez Decl., ¶ 28 & Ex. C at 1. To date, Caremark's attorneys have never sent a response to this email. Rodriguez Decl., ¶ 28. Nor has Caremark produced a single document responsive to the Subpoena or committed to doing so. *Id.*, ¶ 29.

II. LEGAL ARGUMENT

A subpoena served under Federal Rule of Civil Procedure Rule 45 must fall within the scope of proper discovery under Rule 26(b)(1). *Green v. Cosby*, 314 F.R.D. 164, 169 (E.D. Pa. 2016). Pursuant to Rule 26(b)(1), generally “[p]arties may obtain discovery regarding any nonprivileged matter that is relevant to any party’s claim or defense and proportional to the needs of the case . . .” “Relevance in this context has been ‘construed broadly to encompass any matter that could bear on, or that could reasonably lead to other matter that could bear on any issue that is or may be in the case.’” *United States ex rel. Bergman v. Abbott Labs.*, No. 09-cv-4264, 2016 WL 4247429, at *2 (E.D. Pa. Aug. 11, 2016) (quoting *Oppenheimer Funds v. Sanders*, 437 U.S. 340, 351 (1978)); *see also Hicks v. Big Brothers/Big Sisters of America*, 168 F.R.D. 528, 529 (E.D. Pa. 1996).

Under Fed. R. Civ. P. 45(d)(2)(B), the subpoenaed party has 14 days to object to the subpoena after service has been executed, and the failure to timely object constitutes a waiver of the responding party’s objections, especially if those objections are based on relevance or undue burden. *Northfleet Corp. v. Consolidated Rail Corp.*, No. 83-cv-2992, 1984 WL 2615, at *2 (E.D.

Pa. Apr. 27, 1984); *see also, e.g., Boselli v. Se. Penn. Transp. Auth.*, 108 F.R.D. 723, 726 (E.D. Pa. 1985) (“The principle that the failure to timely object to a discovery request constitutes a waiver of the objection has been applied with particular regularity when the objections relate solely to the relevance or burdensomeness of the discovery request.”). Thus, by failing to serve written objections to the Subpoena, Caremark has waived all objections, including as to relevance or undue burden.

In any event, the discovery sought here by Takeda is highly relevant to issues relating to class certification. The putative plaintiff classes in the Actions seek class certification pursuant to Rule 23(b)(3), which requires as a prerequisite “a determination that common questions of fact or law predominate over questions affecting only individual members.” *See In re Fine Paper Antitrust Litig.*, 685 F.2d 810, 822 (3d Cir. 1982); *see also In re Mushroom Direct Purchaser Antitrust Litig.*, 319 F.R.D. 158, 187-88 (E.D. Pa. 2016). Given that Rule 23(b)(3) is an “adventuresome innovation” designed to weed out “situations in which class treatment is not clearly called for,” the court ruling on class certification has a duty to take a “close look” at whether common questions predominate over individual ones. *See Comcast Corp. v. Behrend*, 569 U.S. 27, 34 (2013) (internal quotations and citations omitted).

The requests made in Takeda’s Subpoena—and certainly the modified requests proposed in the August 25 Letter and November 4 Letter—are narrowly tailored to allow Takeda to obtain the information necessary to oppose plaintiffs’ forthcoming motions for class certification. The requests seek information bearing on whether the plaintiff classes are ascertainable and whether plaintiffs can demonstrate antitrust injury and damages through common evidence. *See Rodriguez Decl.*, Ex. F at 2. The fact that each of the other PBMs subpoenaed by Takeda, including Express Scripts—the largest PBM during the relevant time period—have already produced documents and data in response to substantively identical subpoenas confirms that the requests directed to

Caremark seek relevant and discoverable information. *See* Rodriguez Decl., ¶ 30.

Moreover, in the fifteen months since the Subpoena was served, Caremark has failed to present any evidence demonstrating that Takeda’s requested discovery would impose an undue burden or expense on Caremark. *See Burgess v. Galloway, et al.*, No. 20-cv-06744, 2021 WL 2661290, at *3 (D. N.J. Jan. 28, 2021) (explaining that a subpoena is considered unduly burdensome when the Court finds that it is “unreasonable or oppressive”). Pursuant to Federal Rule of Civil Procedure 45(d)(3)(A)(iv), an “undue burden” consists of a “clearly defined and serious injury” to the subpoenaed party. *See* FED. R. CIV. P. 45(d)(3)(A)(iv); *see also Cty. of St. Petersburg v. Total Containment, Inc.*, No. 06-cv-20953, 2008 WL 1995298, at *2 (E.D. Pa. May 5, 2008) (citing *Transcor, Inc. v. Furney Charters, Inc.*, 212 F.R.D. 588, 592-93 (D. Kan. 2003)) (noting that general assertions of competitive disadvantage are insufficient to establish an undue burden).⁴ Here, Caremark has not furnished any evidence to show that compliance with the Subpoena would impose an undue burden on Caremark. When Mr. Davis actually responded to emails from Takeda’s counsel, he simply claimed that the Subpoena was “very broad,” and offered nothing further. *See* Rodriguez Decl., Ex. C at 3. This bald assertion fails to satisfy Rule 45’s definition of an undue burden. Caremark should be compelled to comply with Takeda’s Subpoena.

In short, the Federal Rules of Civil Procedure provide that a party has 14 days to select one of three options in response to a valid subpoena—comply with the discovery requests, respond with formal written objections, or move to quash the subpoena. *Ninaltowski v. Moore*, No. 20-cv-01808, 2021 WL 3051932, at *1 (E.D. Pa. July 20, 2021); *see also* FED. R. CIV. P. 45(d). Caremark chose to do none of the three. Instead, after initially participating in meet-and-confers about the

⁴ At the time the *Cty. of St. Petersburg* opinion, this section was known as Rule 45(c)(3)(A)(iv).

Subpoena, Caremark avoided Takeda's counsel at all costs.⁵ “[I]gnoring the subpoena entirely” is not a valid response. *Ninaltowski*, 2021 WL 3051932, at *1 (emphasis added). An order compelling Caremark to comply with the Subpoena is therefore warranted.

III. CONCLUSION

For the foregoing reasons, Takeda respectfully submits that this Court should grant its Motion to Compel Caremark's compliance with the Subpoena in its entirety.

Dated: July 26, 2023

LAW OFFICES OF STUART J. GUBER

Of Counsel:

ELLIOTT KWOK LEVINE &
JAROSLAW LLP

Mark M. Elliott (*pro hac vice* pending)
Rachel J. Rodriguez (*pro hac vice* pending)
565 Fifth Avenue, 7th Floor
New York, NY 10017
(212) 321-0510
melliott@ekljlaw.com
rrodriguez@ekljlaw.com

/s/ Stuart J. Guber

Stuart J. Guber
150 Sawgrass Drive
Blue Bell, PA 19422
(215) 834-4254
guberlaw@gmail.com

*Attorneys for Plaintiffs Takeda Pharmaceutical
Company Limited, Takeda Americas Holdings,
Inc., Takeda Pharmaceuticals U.S.A. Inc., and
Takeda Development Center Americas, Inc.*

⁵ To the extent that Caremark has asserted a position at all, it appears to be limited to the inaccurate belief that Takeda can obtain the requested information elsewhere, such as from the named EPP or DPP Plaintiffs. As noted, Caremark was the second largest PBM during the relevant time period, making it the best and most accurate source of discoverable information. The limited amounts of information held by the named Plaintiffs is not a substitute and is not sufficient to permit Takeda to fully oppose plaintiffs' motions for class certification.